510(k) Summary

K123375

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. General Information

NOV 20 2012

Establishment:

- Address: Siemens AG, Medical Solutions
  Henkestrasse 127
  D-91052 Erlangen
  Germany
- Registration Number: 3002808157
- Contact Person: Sabine Schroedel
  Regulatory Affairs Manager
  Telephone: +49 (9131) 84-8285
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Device Name and Classification:

- Trade Name: *syngo*.via
- Classification Name: Picture Archiving and Communications System
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description and Intended Use:
This premarket notification covers Siemens' enhanced PACS system *syngo*.via.
syngo.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options. *syngo*.via supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments. The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

The system is a software only medical device. It defines minimum requirements to the hardware it runs on. The hardware itself is not seen as a medical device and not in the scope of this 510(k) submission.

It supports the physician in diagnosis and treatment planning. *syngo*.via also supports storage of Structured DICOM Reports.

In a comprehensive imaging suite *syngo*.via integrates Radiology Information Systems (RIS) to enable customer specific workflows.

syngo.via allows to use a variety of advanced applications (clinical applications) designed for *syngo*.via just as the predicate device *syngo*.x (K0925519, cleared on August 27, 2009). These applications are medical devices on their own rights and filed separately. They are not part of this 510(k) submission and not part of the *syngo*.via medical device. *syngo*.via has a universal component called generic reader application which is part of this medical device and it allows no newly introduced imaging and post processing algorithms compared to the above mentioned predicate devices.

syngo.via is based on Windows. Due to special customer requirements and the clinical focus *syngo*.via can be configured in the same way as the predicate device with different combinations of *syngo*- or Windows -based software options and clinical applications which are intended to assist the physician in diagnosis and/or treatment planning. This includes commercially available post-processing software packages.

<u>*syngo*.via Data Management</u>

... ensures all authorized personnel fast and continuous access to radiological data. It's main functionality ranges from availability of images with regard to data security, open interfaces, storage media and central system administration, to provide a flexible storage hierarchy.

<u>Integration:</u>

The Workflow Management enables by integration of any HL7- / DICOM-compatible RIS (IHE Year 5) to the *syngo* product family a consistent workflow –

from patient registration to requirement scheduling to a personal work list and supports therefore reporting, documentation or administrative tasks.

Technological Characteristics:

syngo.via is a "software only"-system, which will be delivered on CD-ROM / DVD to be installed on common IT hardware. This hardware has to fulfil the defined requirements.

The backend communication and storage solution is based on Windows 2008 operating system. The client machines are based on Windows XP, Windows Vista and Windows 7. Any hardware platform, which complies to the specified minimum hardware and software requirements and with successful installation verification and validation activities can be supported.

The herewith described *syngo*.via supports DICOM formatted images and objects.

The *syngo*.via will be marketed as a software only solution for the end-user (with recommended hardware requirements). Any special needs such as integration in a specific environment and updates / upgrades will be covered by individual service contract and fulfilled by special trained service technicians.
syngo.via will be used for viewing, manipulation, communication, and storage of medical images. The predicate device *syngo*.x is also capable of viewing, manipulation, communication, and storage of medical images.

The difference between the *syngo*.via and the predicate device *syngo*.x are to give the subject device greater capabilities than the predicate device.
syngo.via has similar technological characteristics as the predicate device and is similar to the functionalities of the predicate device, see table below:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

Siemens AG Healthcare SY
% Mr. Norbert Stuiber
Responsible Third Party Official
TÜV SÜD America, Inc.
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

Re: K123375
Trade/Device Name: syngo®.via
Regulation Number: 21 CFR 2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 30, 2012
Received: November 1, 2012

Dear Mr. Stuiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K123315
Device Name: *syngo*®.via

Indications For Use:

syngo.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images.
It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options.

syngo.via supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

Prescription Use X AND / OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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